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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/943,246 09/10/92 LUBON

18N2/0430

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WASHINGTON, D.C. 20007-5109

H 20523/105
EXAMINER

CROUCH, D

ART UNIT PAPER NUMBER

1804

DATE MAILED:

04/30/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on Feb 21, 1996 ☒ This action is made final

A shortened statutory period for response to this action is set to expire 3 month(s), ✓ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-4, 6-9, 11, 12, 14 and 16 are pending in the application.
Of the above, claims 16 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-4, 6-9, 11, 12 and 14 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.129(a). Applicant's first submission after final filed on January 29, 1996 has been entered.

Newly submitted claim 16 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the promoter can be used to produce a recombinant protein in tissue culture cells

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 16 is withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

Claims 1-4, 6-9 and 11-14 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to transgenic mammals and methods of making transgenic non-human mammals selected from the group consisting of mice, rats, rabbits, pigs, sheep and goats which produce biotically active protein C in their milk and methods of producing biologically active protein C selected from the group consisting of mice, rats, rabbits, pigs, sheep and goats. See M.P.E.P. §§ 706.03(n) and 706.03(z). Applicant's species claim to transgenic cows is not enabled by the disclosure, nor are there sufficient teachings in the art for the production of a transgenic cow that the specification does not have to provide guidance for this species. The production of transgenic cows, at least by a review of the art, appears to be problematic. Given the vast numbers of transgenic mammals, other than cows, that

have been produced over the last 10 years, given the rate at which the technology has been improved, especially in mammals as protein producers in milk, and given the large quantity of milk that a transgenic cow would produce, the absence of transgenic cows speaks loudly that the production of transgenic cows is not routine. Therefore, as the artisan can not rely on the art for direction in the production of transgenic cows, it is necessary that the specification provide such direction. In one of applicant's art submissions, work with transgenic cows has been suspended (Genetic Engineering News, Oct. 15, 1995, page 8, col. 5, parag. 3). In the same art, the table refers to transgenic cows under development without any mention of expression and isolation of the desired protein from their milk (Genetic Engineering News, Oct. 15, 1995, page 8). Contrary to applicant's statements, there is nothing routine about making transgenic cows. In fact after a review of the art via data bases, issued patents and applicant's submissions, the production of transgenic cows lacks a prediction of success to achieve a phenotype of producing biologically active protein C in the cow's milk. Additionally applicant has not taught a use for the production of inactive protein C. How such a protein would benefit the art is not apparent. In addition, evidence is not of record that the method disclosed would produce any an all proteins in the milk of such a vast array of mammals. This is especially noteworthy given the submitted art (Genetic Engineering News, above) that

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discloses a companies problems with transgenic cows and rabbits. Thus the skilled artisan would need to engage in an undue amount of experimentation without a predictable degree of success to implement the invention as claimed.

Applicant's arguments have overcome the deposit requirement made in the previous office action.

Applicant's amendments have overcome the rejection under 35 USC 112, 2nd paragraph.

The claims are free of the prior art. At the time of the instant invention, the art did not recognize or suggest the production of protein C in the milk of transgenic non-human mammals.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE

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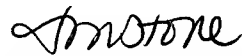
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ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (703) 308-1126.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Dr. D. Crouch
April 23, 1996


JACQUELINE M. STONE
SUPERVISORY PATENT EXAMINER
GROUP 1800